MEDICARE PART D: **CLOSING THE COVERAGE GAP**

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Signed into law on February 9, 2018, the Bipartisan Budget Act (BBA) of 2018 entails significant adjustments to consumer spending under the Medicare Part D prescription drug program.[1] Beginning in 2019, the period of out-of-pocket expenses in Medicare, known colloquially as the coverage gap or donut hole, will be fully covered for beneficiaries. By requiring higher payments from pharmaceutical manufacturers, the BBA of 2018 accelerates the original timeframe laid forth in the Affordable Care Act for closure in 2020.[2]

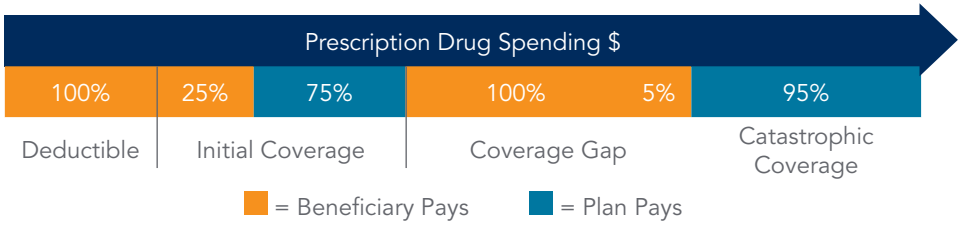
While the long-term effects are open to speculation, industry stakeholders will want to familiarize themselves with the components of this act to better prepare for its potential implications.

BACKGROUND

Medicare Part D Coverage Gap

Enacted as part of the Medicare Modernization Act by George W. Bush, the Part D program was formulated in 2003 and initiated in 2006. Whereas Part A generally covers hospital expenses, and Part B covers medical expenses, Part D was created to cover expenses for prescription drugs. As a part of this program, Medicare eligible seniors would pay for all drug costs up to a deductible, then a partial co-pay up to an initial coverage limit. Once this limit was reached, beneficiaries would pay for all prescription drug costs up to an out-of-pocket threshold, thereby qualifying them for "catastrophic coverage," which would then only require partial co-payment again. This window of payment exposure became known as the coverage gap, or donut hole.[3]

Figure 1 - The chart below depicts the annual prescription drug payment thresholds for Medicare Part D beneficiaries when the Part D program was first enacted

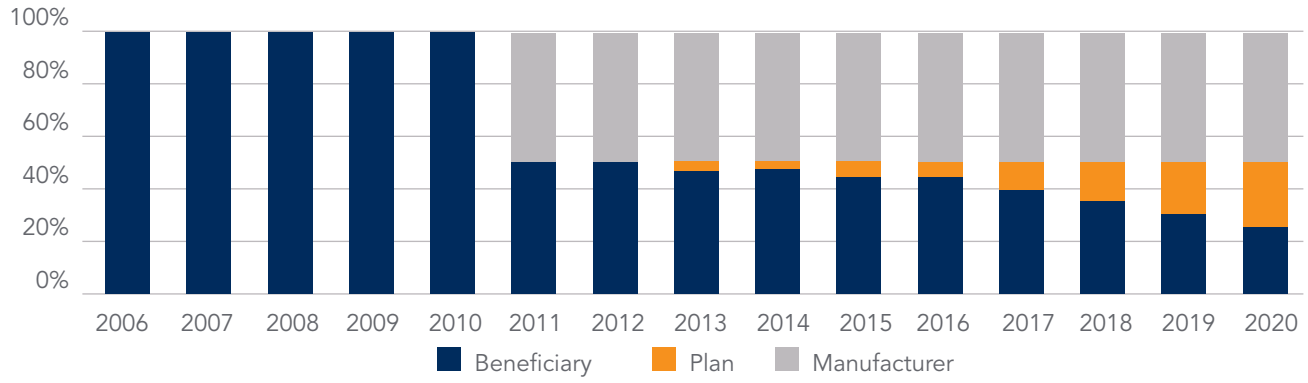


In an effort to further assist beneficiaries, the Affordable Care Act (ACA) initiated the Coverage Gap Discount Program, directing manufacturers and plans to reimburse beneficiaries for a portion of their costs during the donut hole. As part of this same program, a plan to gradually close the coverage gap was also introduced. By annually increasing the payment percentage required from manufacturers and plans, the amount paid by Part D recipients would be reduced on a yearly basis. This would occur until beneficiary costs reached 25% in 2020, thereby equaling the cost sharing mix in the initial coverage phase, and effectively eliminating the coverage gap.[2]

At the time, opinions were mixed as to long-term effects of this decision. Some critics claimed that it undermined the incentive for seniors to opt for less costly generic medications, while others felt that the donut hole was a misguided plan from the beginning.[4 5]

MEDICARE PART D COVERAGE GAP

Figure 2 - The graph below shows the decreasing prescription drug payment amounts required from Medicare Part D beneficiaries in the coverage gap after the change introduced in the ACA6



NEW PART D PROVISIONS

Earlier Coverage Gap Closure

The first major provision in the 2018 BBA affecting Medicare Part D is the expedited closure of the coverage gap in 2019.[1] This adjusts the timeframe laid out in the ACA, which intended to eliminate the donut hole by 2020.[7] In this model, the amount paid by seniors in the coverage gap phase will continue at the same 25% rate as the initial coverage period. Once the catastrophic threshold is reached, beneficiaries will still be responsible for only 5% of total costs.[8]

Manufacturer Rebate Increase

Concurrent with the donut hole closure is an adjustment of the manufacturer coverage gap discount from 50% to 70% for branded drugs, effective also at the beginning of 2019.[1] By contrast, Part D plan sponsors will have their coverage gap payments reduced to 5% in 2019.[7] As a result, beneficiaries will still be responsible for paying 25% of total costs in this timeframe, as originally planned for in the ACA. In effect, this means the cost burden will reside primarily with Part D plans in the initial and catastrophic coverage phases, and primarily with manufacturers for the coverage gap phase.[8]

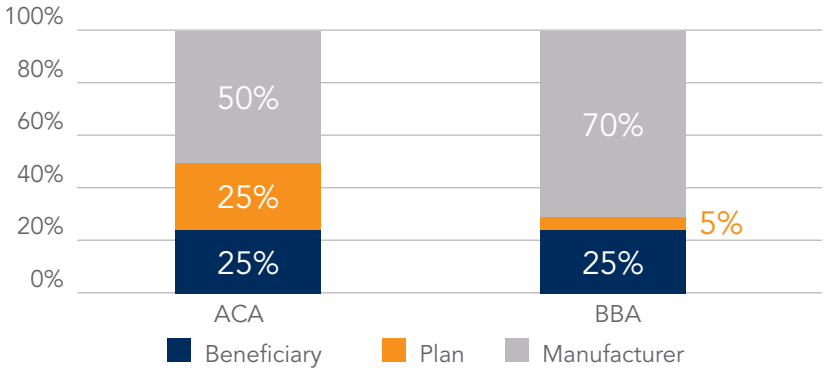


Figure 3 - The graph shows the changes in coverage gap spending required from manufacturers, plans, and beneficiaries introduced in the 2018 BBA, as compared to the original plan in the ACA

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Biosimilar Exclusion Removal

Finally, the new legislation removed the exclusion of biosimilar products from the Coverage Gap Discount Program[1]. Due, in part, to their similarity to traditional generic drugs, these products were previously considered to be ineligible for rebates. Going forward, biosimilars will be reimbursed at the same rates as branded products. Like the other provisions introduced, this change will go into effect as of the beginning of 2019. [7 9]

NEXT STEPS

Considerations

As with any legislative development, predictions about the market response are varied. Given the decreased plan liability in the coverage gap (i.e., from 25% to 5%), it is possible that Part D plans will start to grant more favorable status to brand name drugs, especially if the majority of spending for their patient population falls in this range. Similarly, covered individuals may be more likely to favor brand name drugs if their plan has them in a preferred status, in addition to incurring lower expenses within the coverage gap. For these reasons, branded drug manufacturers may see a corresponding increase in sales and market access within the Medicare channel, which may help to offset the greater rebate payments required. Additionally, if the removal of the coverage gap for beneficiaries does encourage different choices that result in more spending, this may increase the overall expenditure within the catastrophic coverage area.

However, manufacturers of low-margin products, like those in chronic disease states common to elderly populations, may see costs in Medicare rise to untenable levels. Since commercial rebates paid to plans can already be quite sizable in these therapeutic classes, the additional discount provided to beneficiaries might contribute to significantly low net revenue figures. Manufacturers may then seek to recoup funds by lowering rebate rates to plans or raising their prices.[9]

Recommendations
Strategy

To adequately prepare for these changes, pharmaceutical companies with Part D eligible drugs should review their business model, market approach, and pricing strategy around any applicable products. This is particularly imperative for manufacturers with a primary focus in therapeutic classes that are typically associated with aging populations, like diabetes, hypertension, and cardiovascular disease. This also applies to manufacturers with biosimilar products that are now newly eligible for discounts under the program. While a consensus has not been reached as to the effect of product purchase volume through these changes to Part D, it will likely affect individual manufacturers differently based on their customer, contract, and product portfolio.

Operations

Due to the increased coverage gap reimbursement required from manufacturers, an appraisal of any financial modeling is advisable for applicable products. Accruals will need to incorporate the additional discount into ongoing calculations. Similarly, any product lifecycle forecasts should be reviewed to determine if sales will be impacted by these changes, along with a revision of projected liabilities.

Given the intensifying pace of healthcare reform, assessing the effect of these developments and remaining informed about future ones is critical in successfully mitigating issues and adapting to changes.

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About the Author

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Mr. Blank's expertise lies in contracts, pricing, and reimbursement strategies and operations in the life sciences industry. He leverages his expertise to develop and execute revenue management and business process improvement plans for his clients.